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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,717	07/25/2003	Scott E. Andersen	38-21(15878)D	2211

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,717	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-2, 4, and 9-12 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

3. Claims 1-2, 4 and 9-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a substantially purified nucleic acid molecule comprising SEQ ID NO: 11 (claim 1), which encodes a wheat protein or fragment thereof (claim 2), sequences having between 90%, 95%, 98%, 99% and 100% sequence identity with the entire length of SEQ ID NO: 11 (claims 4, 9-12), as well as complete complements thereof. Claims 1 and 2 do not allow for internal variations within SEQ ID NO: 11. Claims 4, and 9-12 allow for internal variations, and further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches that the claimed nucleic acid is an EST isolated from a wheat cDNA library. The claimed invention is not supported by a specific utility because the disclosed

uses of the polynucleotide are not specific and are generally applicable to any EST. The specification discloses many potential uses for the polynucleotide including use as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 13), to determine if genes are members of a particular gene family, to obtain full length genes (page 14), to isolate promoters and flanking sequences (page 32), for use in marker assisted breeding programs, to hybridize to its complement, to encode proteins, to obtain molecules from other plants (page 30), and to determine whether a plant contains a mutation (page 32). These are non-specific uses that are applicable in general to polynucleotides isolated from wheat and not particular or specific to the polynucleotide claimed.

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. For example, the specification teaches that the claimed nucleic acids can be used to identify a polymorphism. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all wheat plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 11. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. The specification provides no indication as to what the nucleic acids are markers for. Polymorphisms

are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 11 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of wheat plant. Therefore, the nucleic acids of SEQ ID NO: 11 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 11 or a protein encoded by SEQ ID NO: 11. SEQ ID NO: 11 may be a portion of a full length open reading frame, but the specification does not teach which protein is actually encoded by SEQ ID NO: 11. For example, it is not clear if nucleotide number 1 is the first nucleotide in a codon, or the last. The specification does not teach an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids.

Likewise, none of the potential promoters, flanking sequences, mutations, or genes that are to be identified as final products resulting from processes involving the claimed nucleic acid

have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, flanking sequences, mutations, and genes does not constitute a specific and substantial utility.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any prior art of record discloses or suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) and *In re Fisher*, 76 USPQ2d 1225 (CAFC 2005). In *Brenner v. Manson*, the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility…[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field…a patent is not a hunting license…[I]t is not a reward for the search, but compensation for its successful conclusion."

In Fisher, the court held that Fisher's asserted uses for ESTs did not qualify as either specific or substantial utilities under *Brenner v. Manson*.

Claim Rejections - 35 USC § 112

4. Claims 1-2, 4, and 9-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

The response traverses the rejections under 35 USC 101 and 112/first paragraph enablement for the same reasons. The response asserts that the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility and cites *In re Fisher*, 76 USPQ2d 1225 (CAFC 2005). The response asserts: "First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Id.* (emphasis in original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*" This argument has been thoroughly reviewed but was not found persuasive to overcome the rejections. It is relevant to point out the following:

A) The present response as well as the response dated October 27, 2008 assert that a BLASTX analysis of the protein sequence encoded by SEQ ID NO: 11 has highly significant correlations with the sequence of acyl ACP desaturase from a variety of plants, including SEQ ID NO: 13 of US Patent 5,723,595, as well as Genbank ID AAB65144, a stearoyl-ACP desaturase from *Helianthus annuus* (present response pages 7-8). The response asserts this is evidence demonstrating a "reasonable correlation" and that Applicants have provided a specific, substantial and credible utility, as well as a well established for SEQ ID NO: 11.

B) In previous responses (11/3/2006, 8/8/2007) Applicants asserted that based on BLAST analysis, SEQ ID NO: 11 correlated to storage proteins in plants and are important in human nutrition and more specifically "The confirmatory BLASTN analysis provides additional

support for Applicants' assertion that SEQ ID NO: 11 *is reasonably correlated* to a wheat storage protein-encoding sequence. A 95 percent identity over 92 percent of the length of a storage protein sequence obtained from *Triticum aestivum* is, without a doubt, a reasonable correlation" (response dated 2/21/2008, page 12).

In other words, although the specification ***does not disclose*** either, on different occasions, Applicants have asserted post filing a "reasonable" correlation ***to two structurally and functionally different proteins*** based on BLASTN or BLASTX analysis.

The response "respectfully reminds the examiner that the utilities asserted in the specification must be accepted as factually sound…". However, it is relevant to point out that the specification does not disclose either utility as a storage protein or utility as an acyl ACP desaturase.

At 2107.02, the MPEP states " If a person of ordinary skill would not immediately recognize a specific and substantial utility for the claimed invention (i.e., why it would be useful) based on the characteristics of the invention or statements made by the applicant, the examiner should reject the application under 35 U.S.C. 101 and under 35 U.S.C. 112, first paragraph, as failing to identify a specific and substantial utility for the claimed invention. The rejection should clearly indicate that the basis of the rejection is that the application fails to identify a specific and substantial utility for the invention.".

The specification at the time the invention was filed only generally discloses that the SEQ ID NOS can have high homology to wheat proteins but does not teach what these wheat proteins are or how they function,. The specification at pages 5-6 provides a general discussion of the different types of BLAST analysis in the "Background of the Invention" and teaches that

BLASTN and BLASTX may be used in concert for analyzing EST data (page 5, line 27). However, these are not utilities for the claimed SEQ ID NO 11, but rather a general discussion as to what types of analysis can be performed with ESTs. Any sequence can be used in a BLAST analysis. The disclosure that BLAST analysis exists and how it is useful is a disclosure of the usefulness of BLAST, not a disclosure of a specific or substantial utility for the claimed SEQ ID NOS. Given that the specification does not disclose a specific or substantial utility for SEQ ID NO: 11, that alignments using BLAST analysis yielded results to structurally and functionally different proteins, as well as the fact that Applicants themselves, on different occasions, have asserted completely different utilities for the same SEQ ID NO:, is evidence that a person of ordinary skill would not immediately recognize a specific and substantial utility for the claimed invention. While applicants are presently asserting that SEQ ID NO: 11 is correlated to an acyl ACP desaturase, no support is found in the specification for this subsequently asserted utility (see MPEP 2107.02). Additionally, it is noted that the response's citation of MPEP 2107.03 has been reviewed, but that this section discusses "Asserted Therapeutic or Pharmacological Utilities". No asserted therapeutic or pharmacological utilities have been made.

In *Brenner v. Manson*, the court held that : "...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion." Here, the specification does not teach whether SEQ ID NO: 11 encodes a protein nor does it teach expression analysis or a function for a protein encoded by SEQ ID NO: 11, or homology to storage proteins or ACP desaturases. The specification provides no teaching of any immediate benefit to the public regarding the sequence of SEQ ID NO: 11. The fact that the responses have asserted "correlations" to structurally and functionally different proteins using BLAST analysis,

and the specification is entirely silent as to whether SEQ ID NO: 11 encodes a protein, or expression analysis or a function for a protein encoded by SEQ ID NO: 11, whether it functions as a storage protein or ACP desaturase illustrates that no immediate benefit has been disclosed by the specification at the time the invention was filed nor was the function of SEQ ID NO: 11 well established in the art at the time the invention was filed.

For these reasons and the reasons already made of record, the rejections are maintained.

5. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a substantially purified nucleic acid molecule which comprises SEQ ID NO: 11 and encodes a wheat protein (claim 2).

The specification teaches the sequence of SEQ ID NO: 11. Claim 1 and SEQ ID NO: 11, per se, meets the written description requirement of 35 USC 112, first paragraph. However, SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. It appears to be a fragment of a larger protein since it was isolated from a Triticum aestivum cDNA library. The specification does not teach the function of the larger protein encoded by SEQ ID NO: 11, and provides no description of the remainder of the coding sequence of which SEQ ID NO: 11 appears to be a part of. It is not clear what peptide is encoded by SEQ ID NO: 11, as the specification does not teach, for example, if nucleotide position #1 of SEQ ID NO: 11 is the first nucleotide in a codon, or the second or third.

Due to the open language "comprising", Claim 1 encompasses a genus of nucleic acid molecules which comprise the sequence of SEQ ID NO: 1, allowing for any combination of nucleotides on either side of SEQ ID NO: 1. Although claim 1 meets the written description requirement as one of skill in the art could determine which sequences comprise SEQ ID NO: 1 vs those that do not, and could therefore distinguish members of the claimed genus, Claim 2 is directed to a subgenus of nucleic acids of claim 1 and is directed to a nucleic acid which encodes a wheat protein, or fragment of a wheat protein. However, the specification does not teach what structural requirements of the genus of nucleic acids comprising SEQ ID NO: 11 make a sequence a wheat protein vs that of another plant, or organism. It is not clear which structural aspects of a nucleic acid comprising SEQ ID NO: 11, distinguish it from "non wheat" proteins. Accordingly, it is not representative of the genus of sequences encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co.

Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to arguments

6. The response traverses the rejection. With regard to claim 2, the response asserts that what is relevant is that claim 2 includes sequences of claim 1 which encode "a wheat protein or fragment of a wheat protein" (page 12). At page 14, the response asserts that if a particular nucleic acid molecule contains the nucleotide sequence of SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 11. This argument has been thoroughly reviewed but was not found persuasive. While the sequence of SEQ ID NO: 11 is common to the genus claimed in claim 2, claim 2 is broadly drawn to sequences comprising SEQ ID NO: 11 and not all sequences comprising SEQ ID NO: 11 necessarily encode a wheat protein as the term "comprising" encompasses any combination of

nucleotides on either side of SEQ ID NO: 11. If this was not the case, then claim 2 would not further limit claim 1. Accordingly, additional criteria are required to define the genus of nucleic acids in claim 2. However, the specification provides no definition to distinguish a "wheat protein" from a "non wheat" protein, and thus does not provide any relevant identifying characteristics to distinguish the subgenus of nucleic acids encompassed by claim 2, from non members. The response cites page 20 as well as pages 64-71 of the specification, however no definition was found. Applicants arguments at page 11, that a BLAST X search shows that nucleic acid molecules falling within the scope of the claim 2 are readily identifiable is not found persuasive because not all possible sequences comprising SEQ ID NO: 11 are necessarily so described in the art. For these reasons and the reasons already made of record, the rejection is maintained.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Mondays from 9:00 AM to 1:00 PM, and Tuesdays & Thursdays from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571) 272-0731. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Jehanne Sitton/
Primary Examiner
Art Unit 1634